

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2 290 BROADWAY NEW YORK, NY 10007-1866

MAY 1 9 2014

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Article number: 7005 3110 0000 5966 5916

Mr. Bill Irvin Regional Compliance Officer Omnicare, Inc. 13 Commerce Avenue Londonderry, NH 03053

Re: RCRA §3007 Information Request

Dear Mr. Irvin:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 etseq.

Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Information Request, the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984.

The State of New Jersey is authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926. Notwithstanding, the EPA has retained its authority to enforce the hazardous waste rules and regulations in the State of New Jersey.

EPA sent Omnicare, Inc. a Notice of Violation and Information Request Letter in October 2013 regarding inspections conducted at its Whippany, Southern New Jersey (Moorestown), and Edison facilities. Based on Omnicare, Inc.'s January 2014 response, EPA has additional questions regarding the facilities' generation and handling of wastes.

Pursuant to the provisions of Section 3007 of RCRA, 42 U.S.C. § 6927, EPA hereby requires that you provide the information requested in Enclosure I, using the instructions and definitions included in Enclosure II.

Please provide the information requested no later than thirty (30) calendar days from receipt of this letter. Requests for additional time must be made within ten (10) calendar days of receipt of this letter and must be justified. A responsible official, officer, or agent of your facility, using the form in Enclosure III to this letter, must sign the response.

Your response to this letter must be mailed to the following address:

Ms. Meghan LaReau
Enforcement Officer
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway, 21st Floor
New York, New York 10007-1866

Failure to provide the information requested is a violation of RCRA Section 3007 and may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. Such penalties may be up to \$37,500 per day per violation.

You may, if you so desire, assert a business confidentiality claim covering all or part of the information herein requested. The claim may be asserted by placing on (or attaching to) the information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as "trade secret," "proprietary," or "confidential". The claim should set forth the information requested in 40 Code of Federal Regulations (hereinafter 40 "C.F.R.") Section 2.204(e)(4). Information covered by such a claim will be disclosed by EPA only to the extent permitted by, and by means of procedures set forth in, 40 C.F.R. Part 2. EPA will review the information to determine the extent of confidentiality of the information, and may, at its discretion, challenge the confidentiality claim pursuant to the procedures set forth at 40 C.F.R. Part 2. If no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to you. If you contend that some or all of the submitted information is entitled to confidential treatment, specify which portions of the information you consider confidential. For each item or class of information that you identify as being subject to your claim, please answer the questions in Enclosure IV, giving as much detail as possible. Please note that you bear the burden of substantiating your confidentiality claim. Conclusory allegations will be given little or no weight in the determination.

This information request is not subject to the requirements of the Paperwork Reduction Act (PRA), as amended, 44 USC Part 3501et. seq. If possible, please submit your response electronically to lareau.meghan@epa.gov. If you have any questions about this letter, please call Ms. Meghan La Reau, of my office, at (212) 637-4067.

Sincerely yours,

Leonard Voo, Chief

RCRA Compliance Branch

Enclosures: Enclosure I - Information Request

Enclosure II - Instructions & Definitions Enclosure III - Certification of Answers

Enclosure IV - Substantiation of Confidential Business Information Claim

cc: Mike Hastry, Chief

Bureau of Hazardous Waste Compliance and Enforcement

Central Field Office, New Jersey Department of Environmental Protection

300 Horizon Center- PO Box 407

Trenton, NJ08625-0407

ENCLOSURE I INFORMATION REQUEST

Omnicare, Inc.

Based on a review of Omnicare, Inc.'s January 2014 Response to EPA's October 2013 NOV/IRL (the "January 2014 Response"), EPA has determined that the following information is required to further evaluate the compliance of Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison:

- 1. Did you receive returned pharmaceutical drugs during the time period January 2010 through April 2011? If so, how were these materials handled at Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison? Were the returns sorted and classified as hazardous waste, and/or sent to another entity for recycling, classification and/or disposal? Please describe the process at each facility including how they were sorted, classified and ultimately disposed. If these materials were sent to another entity, please identify that entity (name, address and telephone number).
- 2. Please indicate the chemical composition and quantity of each waste (solid waste and hazardous waste) generated for each calendar month during the time period July 1, 2010 through April 30, 2011 for Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison. Please include the date of generation. If you are unaware of the types of waste generated in the past, use all means necessary to ascertain the information such as interviews with staff, inventories of products purchased, or inquiries of former yendors.
- 3. If not already provided, please list the amount and type, by EPA waste code, of hazardous waste generated for each calendar month from July 1, 2010 through April 30, 2011 for Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison.
- 4. For wastes determined to be hazardous waste, please describe the manner in which each of the wastes listed above were determined to be hazardous. If an entity other than Omnicare of Whippany, Omnicare of Southern New Jersey, Omnicare of Edison, or Omnicare, Inc., made the waste determination, please include their name, address and telephone number.
- 5. For all other waste, please describe the manner in which any waste listed above, was determined not to be hazardous waste. Please submit copies of any documentation used in making such determinations and all analytical results, including the date(s) of analysis and the analytical methods employed. If an entity other than Omnicare of Whippany, Omnicare of Southern New Jersey, Omnicare of Edison, or Omnicare, Inc., made the waste determination, please include their name, address and telephone number.
- 6. Based on your response to Question 3, above, please describe each facility's generator status (Conditionally Exempt Small Quantity Generator, Small Quantity Generator, or Large Quantity Generator) for each calendar month from July 1, 2010 through April 30,

- 2011. Please note that pursuant to 40 CFR §261.5(e), if a generator generates a total of one kilogram or more of acute hazardous waste in a calendar month, all quantities of that acute hazardous waste are subject to full regulation as a Large Quantity Generator. Acute hazardous wastes are identified in 40 CFR §261.33(e) (i.e. P-listed wastes) and certain listed hazardous wastes in §261.31.
- 7. Please submit copies of all hazardous waste manifests from July 2010 through August 2013 for Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison.
- 8. According to the January 2014 Response, a type of waste listed on invoices was UN2811, toxic solids, organic, N.O.S. (various non RCRA pharmaceutical products). Please describe the chemical composition of each waste listed as UN2811.
- 9. In the January 2014 Response, when asked for details on the management of spent fluorescent lamps, Omnicare Inc., referred to a February 2013 Policy. Did Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison begin to manage their spent lamps as universal waste in February 2013? If not, please indicate when the three facilities starting managing this material as universal waste.
- 10. How were spent fluorescent lamps managed by Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison prior to February 2013or prior to the date specified in your response to question 9 above? Please provide all waste manifests, bills of lading, and any other documentation used to track or otherwise document the disposition of the spent fluorescent lamps.
- 11. Did Omnicare of Whippany, Omnicare of Southern New Jersey and/or Omnicare of Edison make a universal waste determination on spent fluorescent lamps prior to February 2013? Please indicate the date this determination was first made. If so, what was the waste determination and when was the determination made? Please submit copies of any documentation used in making such determinations and all analytical results, including the date(s) of analysis and the analytical methods employed.
- 12. Prior to February 2013, did Omnicare of Whippany, Omnicare of Southern New Jersey and/or Omnicare of Edison dispose or arrange for the disposal by any entity of their spent fluorescent lamps in the municipal trash? If so, please provide the time periods. If not, please indicate how these lamps were discarded, managed or recycled, with appropriate documentation supporting your response.
- 13. Please describe the corporate relationship, including applicable ownership and management structure, between Omnicare Inc., and Omnicare of Whippany, Omnicare of Southern New Jersey and Omnicare of Edison.
- 14. When submitting your response, attach to the Certification of Answers to Request for Information (Enclosure III, below) a list of persons by name, position or title, and company who prepared or assisted in the preparation of the responses to this information request.

ENCLOSURE II INSTRUCTIONS AND DEFINITIONS

Omnicare, Inc.

In responding to this Request for Information, apply the following instructions and definitions:

- 1. The signatory should be an officer or agent who is authorized to respond on behalf of Omnicare, Inc. The signatory must sign the attached Certification of Answers (Enclosure III) and return it with the response to this Request for Information.
- 2. A complete response must be made to each individual question in this Information Request. Identify each answer with the corresponding number listed in Enclosure I.
- 3. In preparing your response to each question, consult with all present and former employees and agents of the facility who may be familiar with the matter to which the question pertains.
- 4. In answering each question, identify all contributing sources of information.
- 5. If you are unable to answer a question in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any question, state that person's name and last known address and phone number and the reasons for your belief.
- 6. If you cannot provide a precise answer to any question, please approximate and state the reason for your inability to be specific.
- 7. For each document produced in response to this Request for Information, indicate on the document or in some other reasonable manner, the number or letter of the question to which it applies.
- 8. If anything is deleted or redacted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion.
- 9. If a document is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.
- 10. The facilities, for the purposes of this Request for Information, are all areas of Omnicare of Whippany located at 121 Algonquin Parkway in Whippany, New Jersey; Omnicare of Southern New Jersey located at 40 Twosome Drive, Suite 1 in Moorestown, New Jersey and Omnicare of Edison located at 120 Fieldcrest Avenue in Edison, New Jersey.
- 11. Hazardous waste and hazardous waste generator are defined, for the purposes of this

Request for Information, as set forth at 40 C.F.R. Part 261.

- 12. *Manage* is defined, for the purposes of this Request for Information, as: to market, generate, treat, store, dispose, or otherwise handle.
- 13. *Universal waste* and *lamps* are defined, for the purposes of this Request for Information, as set forth at 40 C.F.R. Part 273.

ENCLOSURE III CERTIFICATION OF ANSWERS

Omnicare, Inc.

CERTIFICATION OF ANSWERS TO REQUEST FOR INFORMATION

I certify under penalty of law that I have personally examined and am familiar with the information submitted in response to EPA's Request for Information, and all documents submitted herewith; that the submitted information is true, accurate, and complete; and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

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ENCLOSURE IV SUBSTANTIATION OF CONFIDENTIAL BUSINESS INFORMATION CLAIM

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- 1. For what period of time do you request that the information be maintained as confidential, *e.g.*, until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
- 2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to Question 1, immediately above?
- 3. What measures have you taken to protect the information claimed as confidential and to guard against undesired disclosure? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
- 4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
- 5. Has EPA or any other governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
- 6. For each category of information claimed as confidential, explain with specificity why release of the information is likely to result in substantial harmful effects on the business or to its competitive position. Explain the specific nature of those harmful effects; why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
- 7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
- 8. Any other issue you deem relevant.

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